Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT PORTMANN,
URS CHRISTOPH HOFMEIER,
ANDREAS BURKHARD,
WALTER SCHERRER, and
MARTIN SZELAGIEWICZ

Appeal No. 2003-1199
Application No. 09/125,329

ON BRIEF

WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 9, 13, 14, 16 through 21, 26, 28, 30, and 31, which are all of the claims remaining in the application.

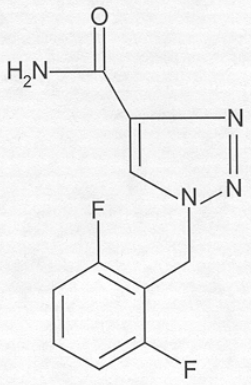
The Invention

The compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide was known in the art at the time applicants' invention was made (specification, page 1). Valuable pharmacological properties have been attributed to this compound; it may be

used, for example, as an antiepileptic (id.). According to applicants, they have surprisingly found that different crystal modifications or polymorphs, characterized at length in their specification, may be prepared by using specially selected process conditions, e.g., an appropriate solvent for recrystallization or the duration of recrystallization (id.). The invention here relates to the novel crystal modifications A and A', and to their preparation and use in pharmaceutical preparations.

Claims 1, 7, 26, and 28, which are illustrative of the subject matter on appeal, read as follows:

1. Crystal modification A of the compound 1-(2,6-difluorobenzyl)-1H-1-2,3-triazole-4-carboxamide of the formula



characterized by characteristic lines at interplanar spacings (d values) of 10.5 Å, 5.14 Å, 4.84 Å, 4.55 Å, 4.34 Å, 4.07 Å, 3.51 Å, 3.48 Å, 3.25 Å, 3.19 Å, 3.15 Å, 3.07 Å, 2.81 Å, determined by means of an X-ray powder pattern.

7. Crystal modification A' of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, characterized in that it is identical to the modification A according to Claim 1, but has defects in the crystal lattice.

26. A pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and a therapeutically effective amount of crystal modification A of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide according to Claim 1.

28. A pharmaceutical composition comprising a pharmaceutically acceptable carrier or diluent and a therapeutically effective amount of crystal modification A' of the compound 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide according to Claim 7.

The References

The prior art references relied on by the examiner are:

Meier (Meier '680)	4,789,680	Dec. 6, 1988
Meier (Meier '262) (European Patent Application)	199,262	Oct. 29, 1986

Muenzel (Muenzel (1966)), "Design and Effect of Pharmaceuticals," Progress in Drug Research, Vol. 10, pp. 227-30 (1966)

Muenzel (Muenzel (1970)), "Design and Effect of Pharmaceuticals," Progress in Drug Research, Vol. 14, pp. 309-21 (1970)

The Rejections

The previously entered rejections under 35 U.S.C. § 102 and 35 U.S.C. § 112 have been withdrawn (Paper No. 16, section (10)).

Claims 1 through 9, 13, 14, 16 through 21, 26, 28, 30, and 31 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Meier '680, Meier '262, Muenzel (1966), and Muenzel (1970). Those same claims also stand

rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 through 10, 14, and 20 of Meier '680 in view of the combined disclosures of Muenzel (1966) and Muenzel (1970). Finally, claims 1 through 9, 13, 14, 16 through 21, 26, 28, 30, and 31 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 through 13, 17, and 21 through 23 of Application No. 09/599,688 in view of the combined disclosures of Muenzel (1966) and Muenzel (1970).

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1 and 2, and all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 14) and the Reply Brief (Paper No. 17); (3) the Examiner's Answer (Paper No. 16); (4) the above-cited prior art references; and (5) "Document 1" and "Document 2, " i.e., the exhibits attached to Paper No. 10 submitted after Final Rejection.[1]

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[1] The examiner's treatment of these exhibits is somewhat ambiguous and not entirely satisfactory. In the Advisory Action mailed January 26, 2001 (Paper No. 11), the examiner does not directly address Document 1 or Document 2 attached to Paper No. 10. In the answer, the examiner states that applicants "failed to show why they [the exhibits] had not been earlier presented" (Paper No. 16, page 5, last line). This suggests that the exhibits were not presented in a timely manner, and therefore not admitted in the administrative record. Nonetheless the examiner assumes that the exhibits are proper. Thus,

> Assuming arguendo that they are indeed proper exhibits, document 1 . . . is in German and not in english [sic]. The exhibit has not been considered. Document 2 fails to establish any superior unexpected

(continued...)

On consideration of the record, including the above-listed materials, we reverse each of the examiner's rejections.

Discussion

The examiner apparently would invoke a per se rule of obviousness, viz., that merely changing the form, purity, or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable. See Ex parte Hartop, 139 USPQ 525, 527 (Bd. App. 1962). The examiner argues that (1) crystal modifications A and A' of 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, recited in the appealed claims, are merely different polymorphic forms of the compound disclosed by Meier '262 in Example 4 or by Meier '680 in Example 35; (2) crystal modifications A and A' recited in applicants' claims and the compound disclosed by Meier '262 or Meier '680 process antiepileptic activity; and (3) accordingly, the subject matter sought to be patented would have been prima facie obvious. We

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[1](...continued)
results for the instant crystals vis-a-viz the known compound. [Paper No. 16, paragraph bridging pages 5 and 6].

On these facts, as best we can judge, both exhibits have been admitted. According to the examiner, however, Document 1 is not entitled to any weight ("the exhibit has not been considered") because applicants did not provide an English translation; and Document 2 is insufficient to rebut the prima facie case of obviousness.

We find it sufficient to note, for reasons presented more fully in the text, that the examiner has not established a prima facie case of obviousness or obviousness-type double patenting. Accordingly, applicants need not rely on the proffered exhibits to rebut any such prima facie case. In the future, we recommend that the examiner be more clear in stating whether exhibits proffered after final rejection have been admitted in the record.

disagree.

First, as stated in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995)

> The use of per se rules, while undoubtedly less laborious than a searching comparison of the claimed invention--including all its limitations--with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. Per se rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on per se rules of obviousness is legally incorrect and must cease.

Second, the principle of law enunciated in Ex parte Hartop, 139 USPQ 525, 527 (Bd. App. 1962) has been substantially discredited in In re Cofer, 354 F.2d 664, 667-68, 148 USPQ 268, 270-71 (CCPA 1966).

Third, on this record, the examiner has not adequately explained how a person having ordinary skill would have been led from "here to there," i.e., from the compound disclosed by Meier '262 in Example 4, or by Meier '680 in Example 35, to crystal modifications A and A' recited in applicants' claims. Having carefully reviewed each Meier reference and the discussion of polymorphism in each Muenzel reference, we disagree that the cited prior art would have led a person having ordinary skill to the specific crystal modifications A and A' recited in the claims on appeal.

Accordingly, the examiner's rejection under 35 U.S.C. § 103(a) is reversed.

All of the appealed claims stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 through 10, 14, and 20 of Meier '680 in view of the combined disclosures of Muenzel (1966) and Muenzel (1970). On reflection, we think it apparent that the rationale of this rejection parallels the rationale supporting the examiner's obviousness rejection under 35 U.S.C. § 103(a).

Accordingly, for reasons already discussed, the rejection on grounds of obviousness-type double patenting is reversed.

We next consider the provisional rejection of claims 1 through 9, 13, 14, 16 through 21, 26, 28, 30, and 31 under the judicially created doctrine of obviousness-type double patenting over claims 1 through 13, 17, and 21 through 23 of Application No. 09/599,688 in view of Muenzel (1966) and Muenzel (1970). This rejection is moot because Application No. 09/599,688 is now abandoned.

For the sake of completeness, we note Application No. 09/871,366, filed May 31, 2001 as a continuation of Application No. 09/599,688, now abandoned. The '366 application issued September 24, 2002 to Portmann et al. (U.S. Patent No. 6,455,556). The claims of the issued patent recite crystal modifications B and C of 1-(2,6-difluorobenzyl)-1H-1,2,3-triazole-4-carboxamide, which are patentably distinct from crystal modifications A and A' recited in the claims before us. A copy of U.S. Patent No. 6,455,556 is enclosed with this opinion.

The examiner's decision rejecting claims 1 through 9, 13, 14, 16 through 21, 26, 28, 30, and 31 is reversed.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
Donald E. Adams Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Lora M. Green Administrative Patent Judge	)

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